#### <u>REMARKS</u>

#### **Preliminary Remarks**

Reconsideration and allowance of the present application based upon the foregoing amendment and following remarks are respectfully requested. Claims 17-31 are currently pending.

On page 2 of the official action, the examiner objected to the specification for failing to provide priority information of the application. The applicants have amended the specification on page 1, line 2 to indicate the proper priority information for this application. In addition, the applicants have amended the specification at page 11, line 10 to indicate the address of the biological depository with respect to the prior deposit of plasmid pZlaccDA. No new matter is believed to have been introduced herein.

New claim 32 is directed to a process for the production of L-amino acids selected from the group consisting of L-lysine, L-aspartic acid, L-asparagine, L-homoserine, L-threonine, L-isoleucine, and L-methionine comprising (a) culturing coryneform bacteria in which at least the endogenous accDA gene comprises a nucleic acid sequence encoding an amino acid sequence as set forth in SEQ ID NO: 3 is amplified, under conditions suitable for the production of the accDA gene product, (b) accumulating the desired L-amino acid in the medium or in the cells of bacteria, and isolating the L-amino acid(s); and wherein said bacteria produce said L-amino acid(s). Support for new claim 32 can be found throughout the specification, for example, on page 6, lines 2-27, Example 3, and originally filed claims 6, 11, and 16.

New claim 33 is directed to a process for the production of an L-amino acid comprising culturing coryneform bacteria under conditions suitable for overexpression of the accDA gene comprising a nucleic acid sequence encoding an amino acid sequence as set forth in SEQ ID NO: 3 and wherein said bacteria produce said L-amino acid selected from the group consisting of L-lysine, L-aspartic acid, L-asparagine, L-homoserine, L-threonine, L-isoleucine, and L-methionine. Support for new claim 33 can be found throughout the specification, for example, on page 6, lines 2-27, Example 3, pg. 11, lines 21-26, and originally filed claims 6, 11, and 16.

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New claims 36 and 37 are directed to the process of claim 33 wherein said vector is pZlaccAD and the host cell expressed the accDA gene. Support for new claims 36 and 37 can be found throughout the specification, for example, on page 11, lines 10-12.

New claims 38-40 are directed to the process of claim 33 whrein either the endogenous accBC gene, dapA gene, or DNA fragment conferring S-(2-aminoethyl) cysteine resistance is overexpressed. Support for new claims 38-40 can be found throughout the specification, i.e., originally filed claims 13-15.

The applicants do not intend by these or any amendments to abandon subject matter of the claims as originally filed or later presented, and reserve the right to pursue such subject matter in continuing applications.

#### Patentability Remarks

## Rejection Under 35 U.S.C. §112, Second Paragraph

On pages 2 and 3 of the official action, the examiner rejected claims 17-31 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Specifically, the examiner alleged claims 17, 22, 28, and 30 recite the phrases "accDA gene is amplified under conditions suitable for the production of the accDA gene product," "which is also amplified," "additionally amplified," and "simultaneously amplified" which the examiner has deemed to be unclear. The examiner further alleged that claim 23 is indefinite for the phrase "at least partially switched off" because this phrase does not enumerate the specific reaction pathways that need to be or can be switched off. In view of the foregoing amendments and remarks, the applicants respectfully traverse the rejection.

Solely for the purpose of expediting prosecution and without prejudice to the applicants' right to seek broader claims in a duly continuing application, the applicants have canceled claims 20, 23, 26 and 27 without prejudice, thereby obviating the rejection.

Amended claim 17 is now directed to a process for the production of an L-amino acid comprising culturing coryneform bacteria under conditions suitable for overexpression of the accDA gene having the nucleic acid sequence comprising SEQ ID NO: 1, and wherein said bacteria produce said L-amino acid selected from the group consisting of L-lysine, L-aspartic acid, L-asparagine, L-homoserine, L-threonine, L-isoleucine, and L-methionine. Support for amended claim 17 can be found throughout the specification, for example, on page 3, lines 18-31 and page 11, lines 21-26. The phrase "accDA gene is amplified under conditions suitable for the production of the accDA gene product" was changed to "culturing coryneform bacteria under conditions suitable for overexpression of accDA gene" which was suggested by the examiner and for which the applicants are grateful.

Amended claim 22 is directed to the process of claim 17, wherein said bacteria further comprises at least one gene other than accDA which is also expressed. The applicants amended the phrase "which is also amplified" to "which is also expressed," as suggested by the examiner. Similarly, the phrases "additionally amplified" and "simultaneously expressed" in claims 28 and 30 were amended to "overexpressed" or "simultaneously overexpressed," as suggested by the examiner.

In view of the foregoing amendments and remarks, the applicants respectfully submit that the rejection of claims 17, 22, 28, and 30 (and claims dependent therefrom) under 35 U.S.C. §112, second paragraph, have now been overcome and should be withdrawn.

# Rejection Under 35 U.S.C. §112, First Paragraph, Enablement Claims 17-25, 28-31

On page 4 of the official action, the examiner rejected claims 17-25, and 28-31 under 35 U.S.C. §112, first paragraph, for allegedly lacking enablement. Specifically, the examiner alleged that while the specification was enabled for a method for producing the amino acids L-lysine, L-aspartic acid, L-asparagine, L-homoserine, L-threonine, L-isoleucine, and L-methionine, it was not enabled for a method of production of any or all L-amino acids. The examiner further alleged that applicants have not taught a single method that can make all L-amino acids by simply amplifying the accDA polynucleotide. The examiner concludes that the applicants have failed to provide sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention encompassed by claims 17-25 and 28-31.

Solely for the purpose of expediting prosecution, and without prejudice to the applicants right to seek broader claims in a continuing application, the applicants have canceled claims 20, 23, 26 and 27 without prejudice, thereby obviating the rejection of these claims.

As discussed above, amended claim 17 is now directed to a process for production of an L-amino acid selected from the group consisting of L-lysine, L-aspartic acid, L-asparagine, L-homoserine, L-threonine, L-isoleucine, and L-methionine, which the examiner acknowledges is enabled by the specification (see page 4, last paragraph of the official action). Claims 18, 19, 21, 22, 24 and 28-30 are ultimately dependent upon claim 17 and therefore, also enabled by the specification.

Claim 31 is now directed to a process for the production of L-amino acids selected from the group consisting of L-lysine, L-aspartic acid, L-asparagine, L-homoserine, L-threonine, L-isoleucine, and L-methionine comprising (a) culturing coryneform bacteria in which at least the endogenous accDA gene having the nucleic acid sequence comprising SEQ ID NO: 1 is amplified under conditions suitable for the production of the accDA gene product, (b) accumulating the desired L-amino acid in the medium or in the cells of bacteria, and (c) isolating the L-amino acids and wherein said baceteria produce said L-amino acids. Support can be found throughout the specification, for example, on page 11, lines 21-26 and page 9, lines 12-18. The applicants submit amended claim 31 is directed to a method of making L-lysine, L-aspartic acid, L-asparagine, L-homoserine, L-threonine, L-isoleucine, and L-methionine which the examiner acknowledges is enabled by the specification.

In view of the foregoing amendments and remarks, the applicants submit that the rejection of claims 17-25 and 28-31 pursuant to 35 U.S.C. §112, first paragraph, for lack of enablement, has been overcome and should be withdrawn.

#### Claim 25

On page 4 of the official action, the examiner also further rejected claim 25 under 35 U.S.C. §112, first paragraph, for allegedly lacking enablement. Specifically, the examiner stated the novel vector has been deposited in a German Collection under the Budapest treaty, but there is no indication in the specification as to the public availability.

The applicant submit herewith a declaration by the undersigned stating the specific microorganism has been deposited under the Budapest Treaty and a receipt of such deposit

accompanies the declaration. Accordingly, the applicants submit that the rejection of claim 25 has been overcome and should be withdrawn.

### Rejection Under 35 U.S.C. §112, First Paragraph, Written Description

On pages 6 and 7 of the official action, the examiner rejected claims 17,21-24, and 26-31 under 35 U.S.C. §112, first paragraph, for allegedly lacking written description. Specifically, the examiner alleged the specification does not contain any disclosure of the structure of all DNA sequences encompassed by the method claims. The examiner further asserted that genus of DNAs that comprise is a large variable genus having different structures. The examiner alleged that the specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.

In response, the applicants submit that claims 17 and 31 are now directed to particular DNA sequences encoding the accDA gene product to be used in the claimed method thereby obviating the rejection of these claims. As discussed above, claim 23 has been canceled without prejudice. Claims 21, 22, 24 and 28-30 are ultimately dependent upon claim 17 and therefore, also fully described by the specification. In view of the foregoing amendments and remarks, the applicants respectfully submit the rejection of claims 17, 21-24, and 28-30 pursuant to 35 U.S.C. §112, first paragraph, for allegedly lacking written description has been overcome and should be withdrawn.

# **CONCLUSION**

In view of the foregoing, the claims are now believed to be in form for allowance, and such action such action is hereby solicited. If any point remains at issue which the examiner feels may be best resolved through a personal or telephone interview, the examiner is strongly urged to contact the undersigned at the number listed below.

Respectfully submitted,
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#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

TILG ET AL.

Feb-18-04 - 15:13

Group Art Unit: 1653

Application Serial No.: 10/024,370

Examiner: M. N. RAO

Filed: December 21, 2001

Title: METHOD TO MONITOR A FERMENTATION PROCESS

February 18, 2004

## DECLARATION OF BIOLOGICAL DEPOSIT IN COMPLIANCE WITH THE BUDAPEST TREATY

Mail Stop Non-Fee Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

- I, Thomas A. Cawley, Jr., hereby state as follows:
- 1. I am an attorney of record for the above-identified patent application, and as such I am authorized to act on behalf of Degussa AG, the assignee of the application.
- 2. Degussa AG is the assignee of the above-identified patent application as evidenced by an assignment from the inventors to Degussa AG.
- 3. Corynebacterium glutamicum strain DSM715/pZlaceDA was deposited with the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSM) under the terms of the Budapest Treaty on April 28, 1999, and assigned accession no. DSM 12787.
- 4. DSM 12787 is a depository in accordance with the Budapest Treaty for the abovedeposited cultures. Should the cells mutate, become non-viable, non-functional, or be inadvertently destroyed, the assignee will replace such cells for at least thirty years from the date of the original deposit, or for at least five years from the date of the most recent request for release of a sample, or for the enforceable life of any patent issued on the above-identified application, whichever period is longest.

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- 5. The deposits have been made under conditions of assurance of (a) ready accessibility thereto by the public if an enforceable patent is granted whereby all restrictions to the availability to the public of the cell lines so deposited will be irrevocably removed upon the granting of the patent, and (b) access to the cell lines will be available during pendency of the patent application to one determined by the Commissioner of Patents and Trademarks to be entitled thereto under applicable statutes and regulations.
- 6. All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Degussa AG

Вv

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